REMARKS

Claims 17-31 and 47 are pending, and have been rejected. Claims 1-16 and 32-46 have been withdrawn. Applicants hereby submit amended independent claim 17 and amended dependent claim 26. Claim 17 has been amended to explicitly state that the core and the sheath of the co-extruded second particles are co-extruded through a co-extrusion die. Claim 26 has been amended to state that the selected opioid antagonist is a different compound from the selected opioid agonist. Withdrawn independent dosage form claims 1 and 7 have been amended to be consistent with the amendment to claim 17.

Claim Rejections Under 35 U.S.C. § 103(a)

The Examiner has rejected claims 17-31 and 47 under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 6,696,088 to Oshlack et al. and as being unpatentable over U.S. Patent Application Publication No. 2003/0157168 to Breder et al. These claim rejections are respectively traversed.

The present claims each require a plurality of first particles which provide a controlled release of an opioid agonist and a plurality of co-extruded second particles which comprise a core containing an opioid antagonist and a sheath which at least partially surrounds the core, wherein the core and the sheath are co-extruded through a co-extrusion die, and wherein the opioid antagonist is sequestered. The present invention provides a novel controlled release opioid agonist dosage form which includes co-extruded second particles comprising sequestered opioid antagonist which are co-extruded through a co-extrusion die to form a core at least partially surrounded with a sheath. By co-extruding the core and the sheath the present dosage form provides a sequestered opioid antagonist in an efficient and effective manner.

Co-extrusion is well known in the art, and differs from standard extrusion. As stated on the co-extrusion webpage of ThomasNet at http://www.thomasnet.com/articles/plastics-rubber/plastic-coextrusion (copy attached as Appendix 1), "[i]n standard extrusion, solid plastic pellets are gravity fed into a forming mechanism, where jacketed compression screws melt and feed the materials into a die," but "[b]y contrast, coextrusion involves multiple extruders forming layered or encapsulated parts." The webpage also states that "[c]oextrusion is the process of pressing two or more materials through the same die to produce a single piece." As shown below, neither cited reference discloses co-extrusion.

The Oshlack patent discloses a dosage form comprising an a controlled release opioid agonist and a sequestered opioid antagonist, wherein the agonist and the antagonist are interdispersed in the dosage form and are not isolated from each other in two distinct layers. Oshlach does not disclose co-extruded second particles which include the sequestered opioid antagonist in a core which is surrounded by a sheath. Oshlack states that the antagonist may be in the form of multiparticulates individually coated with a material which substantially prevents release or may be dispersed in a matrix comprising a material which substantially prevents release. Oshlack further states that when the antagonist is in the form of multiparticulates, the multiparticulates can be in the form of inert beads coated with the antagonist and overcoated with a sequestering material, or may be in the form of a granulation. The sequestered antagonist may also be dispersed in a matrix comprising the sequestering material. The Oshlack patent does not disclose or suggest the co-extruded second particles comprising the sequestered antagonist, as required by each of the pending claims.

The Examiner describes Oshlack's disclosure as "[t]he process for preparing sustained-release matrices are obtained via melt-granulation or melt-extrusion techniques to yield extruded multi-particulates provided within a capsule or extruded multi-particulates provided within a compressed tablet (col. 30, line 8 – col. 32, line 42)" (Office Action, page 7). The Examiner concludes that "[t]his reads on the 'co-extruded' second particles of claim 17." Applicants respectfully disagree. The sustained-release matrices would correspond to the first particles of the present invention, not to the co-extruded second particles comprising sequestered opioid antagonist. It is submitted that there is simply no disclosure in Oshlack which would have made the co-extruded second particles of the present claims obvious.

The Breder application also discloses a dosage form comprising an opioid agonist and a sequestered opioid antagonist. Breder states that, in certain embodiments, the opioid antagonist in a substantially non-releasable form comprises opioid antagonist particles coated with a coating that substantially prevents its release (Paragraph [0095]). The coating may be applied to the antagonist particles by spraying it onto the particles using any suitable spray equipment, such as a fluidized bed system (Paragraph [0130]). Breder also states that the opioid antagonist may be dispersed in a melt-extruded matrix that renders the antagonist substantially non-releasable (Paragraphs [0098] – [0099] and [0123]). Breder does not disclose or suggest providing co-extruded second particles comprising a sequestered opioid antagonist, as required by each of the present claims.

The Examiner states that in Breder "[t]he process for preparing sustained-release matrices are obtained via melt-granulation or melt-extrusion techniques to yield extruded multi-particulates provided within a capsule or extruded multi-particulates provided within a compressed tablet (p. 16, ¶ 0194 – 0213)" (Office Action page 11). The Examiner concludes that "[t]his reads on the 'co-extruded' second particles of claim 17". Applicants respectfully disagree. First, the portion of Breder cited above by the Examiner discusses the preparation of controlled release matrices for the opioid agonist, not the sequestered antagonist particles. Furthermore, there is no disclosure or suggestion of the provision of co-extruded second particles comprising sequestered opioid antagonist, as required by each of the present claims. There is simply no mention made of co-extrusion in Breder.

Withdrawal of the rejections under 35 U.S.C. §103(a) is therefore respectfully requested.

Conclusion

Favorable reconsideration of the patentability of claims 17-31 and 47 in view of the above amendments and remarks is requested. It is respectfully submitted that all claims are in condition for allowance, early notification of which is requested.

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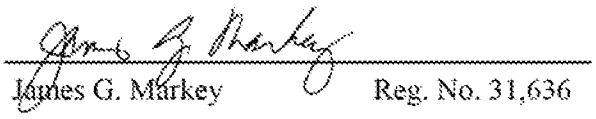
Respectfully submitted,



James G. Markey Reg. No. 31,636

Virtual Law Partners LLP

1979 Marcus Avenue, Suite 210
Lake Success, New York 11042
Tel: (516) 874-4250
Fax: (516) 874-4869